

MEUTERMANS et al
Appl. No. 10/531,303
January 21, 2009

REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

The claims have been revised to recite "the substituents A" rather than referring to Table 1. This revision moots the rejection of claims 14, 17 and 18 under 35 U.S.C. 112, second paragraph, and reconsideration is requested.

Claims 1, 3-6, 8, 14, 22 and 24 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly being non-enabled. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

Applicants respectfully submit that the specification as filed provides a broad range of disaccharide compounds with a broad range of substituents targeted to a range of both gram negative and gram positive bacterial species, including both resistant and sensitive strains. As such, the person skilled in the art would be well positioned to practice the invention without undue experimentation.

The Examiner is reminded that a patent applicant enjoys the presumption that the invention can be practiced as claimed. The burden is on the Examiner to provide evidence to the contrary.

Here, the Examiner relies on the Merck Manual to support her assertion that one skilled in the art "would view that it is highly unlikely that one could inhibit any kind of bacterial growth by contacting any bacterial with any disaccharide of general formula (I)". The Examiner points specifically to the nature of the infections listed in the Manual as being amenable to treatment by administration of aminoglycoside-, macrolide- or linezolid-type antibiotics. The Examiner does not explain, however, why the specificity of these particular types of antibiotics

MEUTERMANS et al
Appl. No. 10/531,303
January 21, 2009

would indicate that the compounds of formula (I) would also be bacteria-specific. Indeed, the Merck Manual teaches that various types of antibiotics, other than aminoglycosides, macrolides and linezolid, provide broad coverage. Since the Examiner has not drawn a nexus between the compounds of formula (I) and aminoglycoside-, macrolide- and linezolid-type antibiotics, the Examiner reliance on the specificity of these types of antibiotics in rejecting the claims as non-enabled is not well founded.

The Examiner has pointed to compound 65 as being ineffective against *S. aureus* but effective against *M. luteus*. Applicants point out, however, that the "+" indicates an MIC below 128 µg/mL while the "-" indicates an MIC above 128 µg/mL. As such, a "-" does not indicate that compound 65 is ineffective but rather that a higher concentration of compound 65 is required to achieve stasis in bacterial growth.

In the last full paragraph on page 6 of the Action, the Examiner contends that the application fails to support the use of the compounds of the instant invention "for the prevention of acute short-term adverse health effects of ionizing radiation exposure in a mammal". Basis for this comment is not seen as Applicants do not claim such a use. Clarification is requested.

Applicants maintain that the skilled person would understand how to take any of the compounds of the invention and inhibit bacterial growth without undue experimentation and with an expectation of success. Accordingly, reconsideration is requested.

Claim 1 stands rejected under 35 U.S.C. 103 as being obvious over Oki et al in view of Sawada et al and Nishio et al. Withdrawal of the rejection is submitted to be in order for the reasons that follow:

As indicated by the Examiner, Oki et al teach that Pradimicin A is an anti-fungal antibiotic that exhibits antibacterial activity against *M. luteus*, a bacterium.

MEUTERMANS et al
Appl. No. 10/531,303
January 21, 2009

Sawada et al teaches that several pradimicin family antibiotics possess potent antifungal activity while their aglycones are inactive against fungi. Sawada et al does not teach the antibiotic activity of these pradimicin family members nor does it teach the activity of the aglycones of these compounds. It is well established that fungal infections are extremely difficult to eradicate and Applicants submit that there is no evidence to suggest that, because the aglycones of the pradimicin family members are inactive against fungi, it would automatically follow that they would be inactive against bacterium.

Nishio et al teaches that pradimicin A has poor solubility in aqueous media contributing to its problem as a drug. The Examiner has chosen to combine this solubility information with the assumption that the aglycone is inactive against bacterium to presume that the carbohydrate component of pradimicin A would exhibit antibacterial activity thereby rendering the instant invention obvious. It is only with hindsight that such a combination could possibly have been made.

Applicants respectfully submit that there are many reasons why the aglycone of the pradimicin family may be inactive against fungi, including the high insolubility. It is more likely that the antifungal activity resides in the aglycone portion of pradimicin A or the entire molecule rather than the carbohydrate portion. Even so, the corollary has not been established with respect to bacterium.

The three cited references were published in 1990 (Oki) and 1993 (Sawada and Nishio). Despite the passage of 15 years, no publication of the antifungal or antibacterial activity of the glycone portions of the pradimicin family could be found in a recent scifinder search.

In view of the above, Applicants submit that the Examiner has not established a *prima facie* case of obviousness. At a minimum, it must be demonstrated that the cited art teaches or

MEUTERMANS et al
Appl. No. 10/531,303
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JAN 21 2009

would have suggested all the claim features. Even assuming, *arguendo*, that the references upon which the Examiner relies teach each claim feature (which Applicants in no way admit is the case), the Examiner must provide basis/motivation for combining these features in the fashion claimed and basis for a reasonable expectation of success. See *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 at 4 (U.S. Apr. 30, 2007) ("A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art"). This, the Examiner has not done.


It will be clear from the foregoing that withdrawal of the rejection is in order and same is requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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